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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert H. DeBellis and Bernard F. Erlanger
Serial No. : 09/828,413
Filed : April 6, 2001
For : METHODS OF TREATING SICKLE CELL DISEASE

1185 Avenue of the Americas
New York, New York 10036
November 2, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

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Sir:

INFORMATION DISCLOSURE STATEMENT

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In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**. Copies of these references are attached hereto as **Exhibits 1-16**, respectively.

1. Adachi, K., M. Ozgue, T. Asakura (1980), "Nucleation-Controlled Aggregation Of Deoxyhemoglobin S Participation Of Hemoglobin A In The Aggregation Of Hemoglobin S In Concentrated Phosphate Buffer", J. Biol. Chem. 255: 3092-3099 (**Exhibit 1**);
2. Ballas, S.K., G.J. Dover, S. Charache (1989), "Effect Of Hydroxyurea On The Rheological Properties Of Sickle Erythrocytes In Vivo", Am. J. Hemotol. 32: 104-111 (**Exhibit 2**);
3. Bunn, H.F. (1997), "Pathogenesis And Treatment Of Sickle Cell Disease", N. Engl. J. Med. 337: 762-769 (**Exhibit 3**);

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4. Charache, S., G.J. Dover, M.A. Moyer, J.W. Moore (1987), "Hydroxyurea-induced Augmentation Of Fetal Hemoglobin Production In Patient With Sickle Cell Anemia", Blood 69: 109-116 (**Exhibit 4**);
5. Charache, S., M.C. Terrin, R.D. Moore, G.J. Dover, F.B. Barton, S.V. Eckert, R.P. McMahon, D.R. Bonds (1995), "Effect Of Hydroxyurea On The Frequency Of Painful Crises In Sickle Cell Anemia", N. Engl. J. Med. 332: 1317-1322 (**Exhibit 5**);
6. Charache, S., and C.L. Conley (1964), "Rate Of Sickling Of Red Cells During Deoxygenation Of Blood From Persons With Various Sickling Disorders", Blood 24: 25-48 (**Exhibit 6**);
7. Dover, G.J., R.K. Humphries, J.G. Moore, T.J. Ley, N.S. Young, S. Charache, A.W. Nienhuis (1986), "Hydroxyurea Induction Of Hemoglobin F Production In Sickle Cell Disease; Relationship Between Cytotoxicity And F Cell Production", Blood 67: 735-738 (**Exhibit 7**);
8. Ferster, A., C. Vermeylen, G. Cornu, M. Buyse, F. Corazza, C. Devalck, P. Fondu, M. Toppet, E. Sariban (1996), "Hydroxyurea For Treatment Of Severe Sickle Cell Anemia: A Pediatric Clinical Trial", Blood 88: 1960-1964 (**Exhibit 8**);
9. Gillette, P.N., C.M. Peterson, S.L. Yang, A. Cerami (1974), "Sodium Cyanate As A Potential Treatment For Sickle Cell Disease", N. Eng. J. Med. 290: 654-660 (**Exhibit 9**);
10. Goldberg, M.A., C. Brugnara, G.J. Dover, L. Shapira, S. Charache, H.F. Bunn (1990), "Treatment Of Sickle Cell Anemia

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With Hydroxyurea And Erythropoietin", N. Engl. J. Med. 323:
366-372 (Exhibit 10);

11. Hahn, E.V., and E.B. Gillespie (1927), "Sickle Cell Anemia: Report Of A Case Greatly Improved By Splenectomy: Experimental Studies Of Sickle Cell Formation", Arch. Intern. Med. 39: 233-254 **(Exhibit 11);**
12. Huisman, T.H.J. and A.M. Dozy (1965), "Studies On The Heterogeneity Of Hemoglobin. IX. The Use Of Tris (hydroxymethyl) aminomethane.HCl In The Ion Exchange Chromatography Of Hemoglobins", J. Chromatog. 19: 160-169 **(Exhibit 12);**
13. Orringer, E.P., D.S. Blythe, A.E. Johnson, G. Phillips, Jr., G.J. Dover, J.C. Park (1991), "Effects Of Hydroxyurea On Hemoglobin F And Water Content In The Red Blood Cells Of Dogs And Patients With Sickle Cell Anemia", Blood 78: 212-216 **(Exhibit 13);**
14. Pauling, L., H.A. Itano, S.J. Sinpur, I.C. Wells (1945), "Sickle Cell Anemia, A Molecular Disease", Science 110: 543-545 **(Exhibit 14);**
15. Steinberg, M.H. (1999), "Management Of Sickle Cell Disease", N. Engl. J. Med. 340: 1021-1030 **(Exhibit 15);** and
16. Rogers, G.P., G.J. Dover, C.T. Noguchi, A.N. Schecter, A.W. Nienbuiss (1990), "Hematologic Responses Of Patients With Sickle Cell Disease To Treatment With Hydroxyurea", N. Engl. J. Med. 322: 1037-1045 **(Exhibit 16).**

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone either of them at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to:
Assistant Commissioner for Patents,
Washington, D.C. 20231.



11-2-01

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